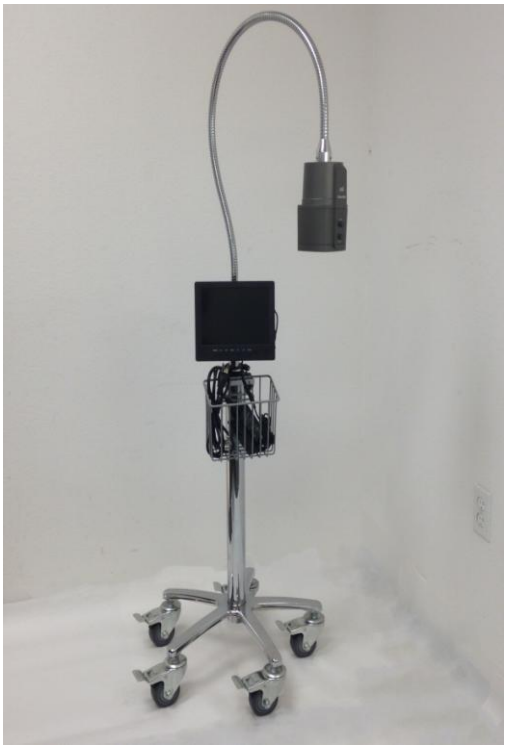
Near Infrared Imaging

VEIN-EYE™ Hospital Cart (HC) - $2,499 - USA

The MSRP will vary internationally due to the costs of shipping, Customs, import fees, insurance and taxes



Drawing blood or starting an IV can be a very challenging task, even for the skilled medical professional. The Vein-Eye makes this task easier. The technology of the Vein-Eye is especially important in patients who are very young, aged, obese, have dark skin, or their veins have collapsed.

The patented technology of the Vein-Eye provides real-time video of sub-dermal veins located on various parts of the body, particularly the patient's arm or hand. The video displays a "runway" image of the patient's vein, necessary for IV placements.

The Vein-Eye HC uses harmless near-infrared light to locate veins and display high-quality images on a monitor. There is no radiation and the light source is an array of LEDs.

Everyone who starts IVs or draws blood knows how difficult and frustrating it is to obtain venous access in many patients. Factors such as small vessel size, fragility, skin pigmentation, edema, adipose tissue, and other issues can make venous access challenging to even the most experienced clinician.

There are no tools required for assembly. The Vein-Eye hospital cart is a well-constructed portable device that will fit easily into a corner, near a bed, or next to a wheelchair.

The warranty is twelve (12) months from the day the unit ships.

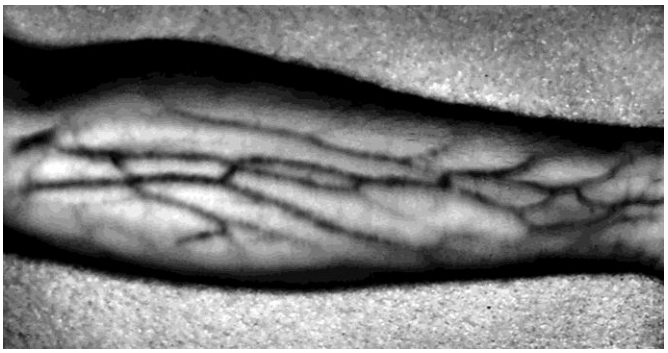
Benefits

*Increase in the number of "first-stick" successes,
*Saves time and improves staff efficiency,
*Improves patient satisfaction ratings for pain management, one of the HCAHPS survey measures,
*Decreases medically-unnecessary PICC lines, reducing cost and infection risk associated with the placement and maintenance of central catheters,
*Reduces escalation calls,
*Decreases the potential for pain and suffering caused by accidental needle sticks.

Advantages

*Affordable
*Rapid assessment of all veins due to a large viewing area,
*Rapid assessment of all veins due to the ability to zoom in and focus on the best vein segment,
*Clear, unobstructed view of the patient by showing veins on a monitor,
*Lightweight, easy to transport, and a small footprint for easy access to the patient's bedside.

Below is an untouched picture of an arm displayed on the Vein-Eye monitor. The arm belongs to the inventor of the Vein-Eye. The Vein-Eye images can also be displayed on a PC or other PDA device.



Properly Using the Vein-Eye

*****Do not attempt to use the Vein-Eye when the camera or the patient is in direct sunlight.

*The camera should be held approximately 10 inches to 18 inches from the patient.

*The patient's arm or hand should lie on a non-glare white background.

*The Vein-Eye was designed for use on white linen on hospital beds, doctors' offices, and phlebotomy chairs.

***The end user should not adjust the fixed internal camera and monitor settings.**

*The camera and monitor are configured at the factory.

*Please consult the User Manual and Assembly Manual for all warnings and specific directions.

Vein-Eye HC Specifications in inches, feet, pounds and Fahrenheit

- Out-of-the-box operating dimensions: When extended vertically: 62” maximum, 54.6 minimum”
- Weight: 29 pounds
- Width: 18.5”

- In-the-box shipping dimensions: 23” X 23” X 16”

- In-the-box shipping weight: 32 pounds

- Operating temperature in storage or in transport: 39.02^{o}F to 104.9^{o}F

- Operating humidity in storage or in transport: 5.1% to 86% relative humidity, non-condensing

- Power: Electrical power is obtained by connecting to a publicly provided power source by means of the 12V (volt), 2.0A (amps) power adapter and power splitter

- Input: 100-240 V AC, 50/60 Hz, 0.8-4 A

- Near infrared wavelength: 850nm

- Output to camera and monitor: 12V DC, 2.5 A

- The Vein-Eye works with either 110V or 220V and adjusts automatically.

Vein-Eye HC Certifications and Registrations

FDA, Class 1, 510K Exempt

CE Marking with the Declaration of Conformity on file

NII’s manufacturer is ISO 13485 and ISO 9001 certified

The Tariff Commodity Code is: 9006.30 - Schedule B

Country of Origin and Certificate to Foreign Governments on file

GTIN and UPC registrations, and barcodes, are available upon request

The Vein-Eye successfully passed the IEC 60601-1, (3rd edition), General requirements for basic safety and essential performance.

a. Standard: IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
b. Test Report Form No: IEC60601_1G
c. Test Report Form Originator: Underwriters Laboratories Inc.
d. The testing was signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02. IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.
e. The CB testing laboratory was done by Intertek Testing Services NA, Inc., 7250 Hudson Blvd, Suite 100, Oakdale, MN 55128, USA

The Vein-Eye successfully passed the Class A for Emissions, Immunity for Non-Life Supporting Equipment

a. Report Number: 101641790MIN-004A
b. Project Number: G101641790
c. Testing performed on the Vein-Eye to IEC 60601-1-2:2007 / IEC 60601-1-2 (ed.3), Class A for Emissions, Immunity for Non-Life Supporting Equipment.
d. The Conducted Emissions measured result in this report is within the specification limits by more than the measurement uncertainty; the measured result indicates that the product tested complies with the specification limit.
e. The Radiated Emissions measured result in this report is below the specification limit by a margin less than the measurement uncertainty; it is not therefore possible to determine compliance at a level of confidence of 95%. However, the measured result indicates a higher probability that the product tested complies with the specification limit.
f. Test Standards: IEC 60601-1-2:2007

    i. Class A Radiated and Conducted Emissions
    ii. Immunity for Non Life-Supporting Equipment

The Listing Constructional Data Report for the Vein-Eye was issued on September 3, 2014.

ANSI/AAMI ES60601-1:2005/A1:2012 Issued: 2012/08/20 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, Amend #1

CSA C22.2#60601-1 Issued: 2008/02/01 Ed:2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; COR 2: 2011/06/01

In addition, NII completed over 300 pages of the required Risk Management File.

The Vein-Eye is assembled in the USA with some foreign parts.

Vein-Eye™ Attached Unit (AU) - $2,199 – USA

The MSRP will vary internationally due to the added costs of shipping, Customs, import fees, insurance and taxes

Drawing blood or starting an IV can be a very challenging task, even for the skilled medical professional. The Vein-Eye makes this task easier. The technology of the Vein-Eye is paramount in patients who are very young, aged, obese, have dark skin, or their veins have collapsed.

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The Vein-Eye HC uses harmless near-infrared light to locate veins and display high-quality images on a monitor. There is no radiation and the light source is an array of LEDs.

Everyone who starts IVs or draws blood knows how difficult and frustrating it is to obtain venous access in many patients. Factors such as small vessel size, fragility, skin pigmentation, edema, adipose tissue, and other issues can make venous access challenging to even the most experienced clinician.

The warranty is twelve (12) months from the day the unit ships. All products are shipped FOB from our manufacturer in Fremont, CA, USA

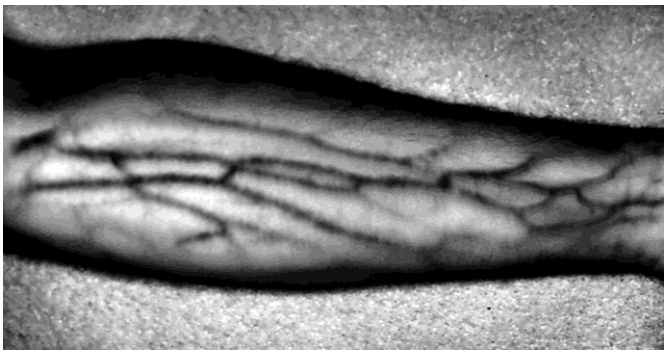
Benefits

*Increase in the number of "first-stick" successes,
*Saves time and improves staff efficiency,
*Improves patient satisfaction ratings for pain management, one of the HCAHPS survey measures,
*Decreases medically-unnecessary PICC lines, reducing cost and infection risk associated with the placement and maintenance of central catheters,
*Reduces escalation calls,
*Decreases the potential for pain and suffering due to accidental needle sticks.

Advantages

*Affordable
*Rapid assessment of all veins due to a large viewing area,
*Rapid assessment of all veins due to the ability to zoom in and focus on the best vein segment,
*Clear, unobstructed view of the patient by showing veins on a monitor,
*Lightweight, easy to clamp onto a chair or bed, and takes up a small amount of space for easy attachment to a fixture/furniture and easy access to the patient.

Below is an untouched picture of an arm displayed on the Vein-Eye monitor. The arm belongs to the inventor of the Vein-Eye. The Vein-Eye images can also be displayed on a PC or other PDA device.



Properly Using the Vein-Eye

*Do not attempt to use the Vein-Eye when the camera or the patient is in direct sunlight.

*The camera should be held approximately 10 inches to 18 inches from the patient.

The patient's arm or hand should lie on a non-glare white background.

The Vein-Eye was designed for use on white linen on hospital beds, doctors' offices, and phlebotomy chairs.

*__The end user should not adjust the fixed internal camera and monitor settings.__

*The camera and monitor are configured at the factory.

*Please consult the User Manual and Assembly Manual for all warnings and specific directions on the use and assembly.

Vein-Eye AU Specifications in inches, feet, pounds and Fahrenheit

Maximum height when extended vertically is 34" maximum
Weight: 7.5 pounds
Width: 6.5"

Shipping in-the-box dimensions: 23" x 23" x 12" (thickness)

Shipping-in-the-box weight: 12 pounds

Operating temperature in storage or in transport: 39.02^{o}F to 104.9^{o}F

Operating humidity in storage or in transport: 5.1% to 86% relative humidity, non-condensing

Power: Electrical power is obtained by connecting to a publicly provided power source by means of the 12V (volt), 2.0A (amps) power adapter and power splitter.

Input: 100-240 V AC, 50/60 Hz, 0.8-4 A

Near infrared wavelength: 850nm

Output to camera and monitor: 12V DC, 2.5 A

The Vein-Eye works with either 110V or 220V, and adjusts automatically to any changes between 100V – 240V.

Vein-Eye Certifications and Registrations

FDA, Class 1, 510K Exempt

CE Marking with the Declaration of Conformity on file

NII's contract manufacturer is ISO 13485 and ISO 9001 certified

Tariff Commodity Code: 9006.30 - Schedule B

Country of Origin is available upon request

Certificate to Foreign Governments is available upon request.

GTIN and UPC registrations, and barcodes, are available upon request.

The Vein-Eye successfully passed the IEC 60601-1, (3rd edition), General requirements for basic safety and essential performance.

a. Standard: IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
b. Test Report Form No: IEC60601_1G
c. Test Report Form Originator: Underwriters Laboratories Inc.
d. The testing was signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02. IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.
e. The CB testing laboratory was done by Intertek Testing Services NA, Inc., 7250 Hudson Blvd, Suite 100, Oakdale, MN 55128, USA

The Vein-Eye successfully passed the Class A for Emissions, Immunity for Non-Life Supporting Equipment

f. Report Number: 101641790MIN-004A
g. Project Number: G101641790
h. Testing performed on the Vein-Eye to IEC 60601-1-2:2007 / IEC 60601-1-2 (ed.3), Class A for Emissions, Immunity for Non-Life Supporting Equipment.
i. The Conducted Emissions measured result in this report is within the specification limits by more than the measurement uncertainty; the measured result indicates that the product tested complies with the specification limit.
j. The Radiated Emissions measured result in this report is below the specification limit by a margin less than the measurement uncertainty; it is not therefore possible to determine compliance at a level of confidence of 95%. However, the measured result indicates a higher probability that the product tested complies with the specification limit.
k. Test Standards: IEC 60601-1-2:2007

    i. Class A Radiated and Conducted Emissions
    ii. Immunity for Non Life-Supporting Equipment

The Listing Constructional Data Report for the Vein-Eye was issued on September 3, 2014

ANSI/AAMI ES60601-1:2005/A1:2012 Issued: 2012/08/20 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, Amend #1

CSA C22.2#60601-1 Issued: 2008/02/01 Ed:2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; COR 2: 2011/06/01

The evaluation period was from June 11, 2014 to September 02, 2014

In addition, NII completed over 300 pages of the required Risk Management File in support of the Vein-Eye HC and Vein-Eye AU. The Vein-Eye is assembled in the USA with some foreign parts.